

EXHIBIT 3

DECLARATION OF THE GEORGE WASHINGTON UNIVERSITY

I, Robert H. Miller, PhD, declare as follows:

1. I am the Interim Vice Provost for Research and the Vice Dean for Research and Academic Affairs in the School of Medicine and Health Sciences at The George Washington University (“GW” or “the University”) in Washington, D.C. I have held the Interim Vice Provost for Research position since August 2024 and previously served as the Vice President for Research at GW from August 2018 to August 2020. Before joining GW in 2014 as the Senior Associate Dean for Research in the School of Medicine and Health Sciences, I was the Vice President, Research & Technology Management at Case Western Reserve University.

2. As Interim Vice Provost for Research, I have personal knowledge of the contents of this declaration, or have knowledge of the matters described herein based on my review of information and records gathered by GW personnel, and could testify thereto.

3. GW receives substantial annual funding from the National Institutes of Health (“NIH”). For fiscal year 2024, GW had approximately \$87 million in NIH funds, approximately \$21 million in indirect costs funded by NIH, and approximately 150 active projects funded by NIH.

4. The funding GW receives from NIH supports critical and cutting-edge biomedical research, which millions of Americans benefit from and depend on. For example:

- a. The University’s cancer research includes enabling, targeting, and suppressing the disease at the earliest stages. The GW Cancer Center boasts complex and innovative research facilities dedicated to cancer discovery through interdisciplinary collaboration and partnerships with scientists and clinicians throughout the GW community. These collaborations and partnerships facilitate

novel approaches to cancer diagnosis and treatment in areas such as clinical and translational oncology and cancer biology and immunology. Additionally, GW researchers focus on cancer prevention via understanding how exposure related smoking, vaping and marijuana usage can be prevented.

- b. Through NIH funding, GW researchers are making great strides in neuroscience and associated disorders and diseases. For example, a GW researcher is an internationally recognized expert in the care of patients with myasthenia gravis, a chronic autoimmune neuromuscular disease characterized by varying degrees of weakness of the skeletal (voluntary) muscles of the body. His research has been funded by the NIH since 1993 and focuses on understanding the biology and pathogenesis of myasthenia gravis. Other GW researchers are doing groundbreaking research that could be the foundation for novel therapeutics for diseases such as Multiple Sclerosis and Neuroinflammation. Other researchers focus on the epidemiology and prevention of Alzheimers and other causes of dementia.
- c. GW advances, develops, and implements innovative practical methods for the design, execution, data monitoring, analyses, and reporting of clinical studies and for the conduct of long-term cohort studies. Current projects include the design and analyses of studies that focus on patient-focused outcome measures that integrate efficacy and safety, personalized treatment, cost-effectiveness analyses, response-adaptive randomization, and pragmatic evaluation of diagnostic technologies. Other studies involve longitudinal analyses of data over many years to understand the progression of disease outcomes and

prevention of adverse consequences like death and disability. An example of both of these types of studies work is the impactful research we have conducted on maternal fetal welfare. The Maternal Fetal Medicine Units Network (“MFMU”) has existed since 1986, and GW serves as the data coordinating center and one of 14 clinical centers. The MFMU has a total of 61 studies (33 randomized trials and 28 observational studies) that have been completed or are in process. As of January 2024, MFMU investigators have made over 640 presentations and published over 400 peer-reviewed manuscripts. The major aims of the MFMU are to reduce the rates of preterm birth, fetal growth abnormalities, newborn morbidity, and maternal complications of pregnancy; secondarily to evaluate maternal and fetal interventions for efficacy, safety, and cost-effectiveness; and ultimately to assess the long-term consequences in terms of health and wellbeing over a lifetime.

- d. Another example is a large clinical trial – the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (“GRADE”), --which compares the effectiveness of the four most commonly used therapies in over 5,000 participants with Type 2 Diabetes over a period of up to ten years. The study is publishing seminal papers to inform clinicians of which combination of diabetes medications achieves the best glycemic control, has the fewest side effects, and is most beneficial for overall good health in terms of preventing the adverse consequences of diabetes (death, vision loss and loss of limbs). This work builds on many years of GW research in prevention of adverse consequences of both Type I and Type II diabetes which have led to current

recommendations not only on therapy but also lifestyle interventions (the “Diabetes Prevention Program”) to prevent diabetes.

e. GW’s Office of Clinical Research (“GW OCR”) provides high-quality support for the efficient execution and management of impactful clinical research while ensuring research participant safety. GW OCR partners with faculty and investigators to coordinate services for:

- i. Researchers, by assisting with study start up and quality
- ii. Patients, by providing information on ongoing clinical studies
- iii. Sponsors, by helping network GW investigators
- iv. Training, Education, and Resources

5. Indirect costs are essential for supporting this research. The NIH’s proposal to cut indirect cost rates to 15% would end or seriously jeopardize all of the research projects described in paragraph 4 as well as other NIH-funded research projects at GW.

6. Indirect costs include the creation and maintenance of critical infrastructure and facilities required to meet the current technical requirements of research, as well as the procurement and maintenance of equipment necessary to conduct such research. Equipment needed for this ground-breaking research goes beyond the standard lab equipment and may be very specialized, such as certain equipment used in GW’s Nanofabrication and Imaging Center and a genomics core. Infrastructure also includes cyber infrastructure and high-performance computing allowing researchers to analyze data and model future outcomes. Without this equipment and infrastructure, GW researchers cannot conduct this research.

7. For example, with respect to some of the areas of research described in Paragraph

- a. With robust programs in cancer biology; cancer control; cancer engineering and technology; and cancer immunology and microbial oncology, the GW Cancer Center facilities support medical lab functions that require significant lab equipment. Cell sorting/isolation, cell therapies and molecular histology and characterization are core activities of the GW Cancer Center. This work is further supported by the GW Nanofabrication and Imaging Center previously mentioned.
- b. The studies on neurological diseases utilize a novel approach to assess the efficacy of drug treatment using high-resolution video recording and specialty-designed computer software analytic tools. This novel approach allows the physician to assess the progress of the patient without the need for the patient to travel to the physician's office. This novel tele-health program is particularly important in rural areas that may be underserved by local medical facilities.
- c. The coordination and facilitation of clinical research requires a large investment in systems and infrastructure to safely and securely collect, manage, analyse, transfer and store electronic data. Systems like Encore, Florence and REDCap aid in the compliant use of human subjects data.

8. Physical space costs are one of the largest components of indirect costs which are elevated due to our location, and the amount of space available to researchers has a direct and immediate impact on the amount of research that can be done at GW. GW's urban location poses unique opportunities and challenges. To maximize space utilization, GW has many shared spaces and facilities that require continuous updating to stay on pace with the novel research taking place by multiple investigators. With the reduction in indirect cost funding, GW will be unable to

properly maintain existing equipment and/or would have to reduce procurement of new equipment limiting the type and quantity of research our investigators can pursue. This funding is essential to the maintenance and development of advanced computing and cyber capabilities needed to protect intellectual property and provides support for research security, e.g. data management, security and analysis.

9. In addition, indirect costs fund the administration of awards, including staff who ensure compliance with a vast number of regulatory mandates from agencies such as NIH.¹ These mandates serve many important functions, including protecting human and animal subjects involved in research; ensuring research integrity; properly managing and disposing of chemical and biological agents used in research; assessing, managing, and preventing financial and other types of conflicts of interest; managing funds; preventing intellectual property, technologies, or national security expertise from being inappropriately accessed by foreign adversaries; and providing the high level of cybersecurity, data storage, and computing environments mandated for regulated data. Adherence to these mandates supports a responsible and ethical approach to biomedical research and creates an environment where reproducibility and validity are of great importance.

10. Recovery of GW's indirect costs is based on predetermined rates that have been contractually negotiated with the federal government.

11. Through fiscal year 2025, the predetermined indirect cost rates are 61.5% for the GW On Campus, 26% for the GW Off Campus and the Biostatistics Center, and 36.5% for the Other Sponsored Activities.²

¹ <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>

² GW's average indirect cost rate for fiscal year 2024 was inadvertently misstated in Plaintiffs' Complaint at Paragraph 67. The Complaint states: "GWU receives significant federal funds from NIH—approximately \$87 million in fiscal year 2024, at an average indirect cost rate of 24% or

12. The impact of a reduction in the indirect cost rate would be devastating. The NIH sponsors more than one-third of GW’s research activity. As of fiscal year 2024, \$300 million of NIH funding has been obligated to GW for active awards, spanning current and future performance periods. Of that, for fiscal year 2024, GW has received \$87 million in NIH funding, approximately \$66 million of which was allocated for direct costs, \$22 million of which was allocated for subcontracts (which are not eligible for overhead recovery), and \$21 million of which was allocated for indirect costs. Similarly, in fiscal year 2025, GW expects to receive \$69 million in NIH funding for direct costs, while \$22 million is allocated for indirect costs. Over the next five years, GW anticipates receiving an average of \$80 million from the NIH for annual direct costs. Based on the predetermined indirect cost rate of 61.5%, which the federal government agreed upon as of March 29, 2023, GW anticipates receiving approximately \$25 million in indirect cost recovery annually, based on current and projected funding levels.

13. If—contrary to what GW has negotiated with the federal government—the indirect cost rate is reduced to 15%, that would reduce the University’s anticipated annual indirect cost recovery for fiscal year 2025 to \$7 million, instead of the anticipated \$22 million, which is a \$15 million reduction.

14. This reduction will have deeply damaging effects on GW’s ability to conduct research from the day the 15% indirect cost rate goes into effect. Most critically, it will necessarily and immediately result in staffing reductions across the board. For example:

- a. GW’s Institutional Review Board (“IRB”) is charged with reviewing and managing all research involving human subjects to ensure the ethical treatment

\$21 million.” Compl. ¶ 67. In that sentence, “24%” should instead read “61.5%.” All other allegations regarding GW in the Complaint are correctly stated.

of subjects and the protection of their privacy. Without appropriate funding for indirect costs, the University may have to reduce staffing on the IRB, which would immediately impact its ability to promptly review research projects involving human subjects. That would in turn lead to substantial delays in critical research that relies on human subjects, including projects funded by NIH.

- b. Additionally, the University's Responsible Conduct of Research ("RCR") team is responsible for ensuring that all individuals engaged in the GW research enterprise understand the importance of adhering to professional standards in specific research fields as well as NIH requirements for training in ethical and responsible conduct of research. The RCR's work enables GW to produce trustworthy research results upon which peers and the general public can rely. A sudden and/or significant reduction of indirect costs will directly impact the number of staff that are dedicated to this integral part of the research ecosystem and GW's ability to support and train its research staff in the ethical and responsible conduct of research.
- c. Furthermore, reduction of indirect costs will significantly hamper research administration across the board. GW will have to reduce the number of staff who support the administrative side of doing research. This will hinder proposal review/preparation and slow the review, approval, and posting of allowable charges to awards, all critical to GW's efforts as stewards of federal research funds.

15. The impact of a reduction of the indirect costs on existing awards will immediately result in a budget deficit that will have GW scrambling to cover unplanned expenses. GW will have to make significant adjustments to try to locate other sources of funding to support its research infrastructure. Cross-cutting measures will include a significant reduction in research and research administration staff and the elimination of important research and development (“R&D”) projects and programs across the University, including halting studies and clinical trials which may result in safety concerns. Stalling current progress in the development of life-saving drugs and cutting technologies will impact the U.S.’s standing as a global leader in R&D. Cuts in funds for infrastructure maintenance will potentially set back the overall research environment, from existing facilities to ongoing collaborations across institutions to advance U.S. R&D and competitiveness in the world. Lastly, abruptly stopping on-going research projects is essentially throwing away the funding already put forth, particularly for long-term projects and those close to producing outcomes and results.

16. GW has for decades relied on the payment of indirect costs. And until now, it has been able to rely on the well-established process for negotiating indirect cost rates with the government to inform its budgeting and planning. Operating budgets rely on an estimate of both direct and indirect sponsored funding to plan for annual staffing needs (*e.g.*, post-docs, PhD students, and other research staff), infrastructure support (*e.g.*, IT networks, regulatory compliance, and grant management support), and facility and equipment purchases. In some cases, GW has long-term obligations—for example, tenured faculty salaries, graduate research assistants’ compensation and tuition packages—and it relies on budgeted grant funding, including associated indirect cost recovery, to fulfill these commitments.

17. In addition to the immediate impacts and reliance interests described above, there are longer-term impacts that are both cumulative and cascading. The longer-term harms are vast and may negate the great strides already made in biomedical research. For example, safety issues from lack of staff/security, as well as the inability to restart clinical trials even if funding were restored, which may put the safety of human subjects at risk through the premature cessation of treatment. Temporary cessation of clinical trials may negate prior work on the trial since patient accrual, reproducibility, and validity of outcomes will be adversely affected. Longer-term effects also include limiting GW's ability: to protect sensitive data from cyberattacks; to comply with U.S. export control laws that secure certain types of information, technologies and commodities, and ensure they are not transmitted overseas to entities and individuals, including U.S. citizens, or made available to foreign nationals on U.S. soil; and to identify, manage and report conflict of interest and other support disclosures in a manner compliant with NIH policies to ensure proper stewardship of NIH funds. The lack of maintenance of lab facilities, compliance and grant management systems, and data repository and cyber infrastructure will further erode the ability to comply with regulations and meet the high standards that lead to research breakthroughs that directly affect society.

18. Disruptions to GW's research will also have negative effects in the Washington Metropolitan area, the District of Columbia, and the broader region. GW employs approximately 11,500 people, with the vast majority residing in the Washington Metropolitan area not including those employed via contractual arrangements. GW collaborates with state and local partners to help solve regional challenges through joint research and innovation. GW's research also fuels spending in the regional economy, including by driving discoveries that launch new ventures, attract private investment, and make a positive social impact. A massive reduction in GW's

research budget would immediately and seriously jeopardize these contributions to the local region.

19. Finally, slowdowns or halts in research by GW and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance.

20. Nor can GW cover the funding gap itself. While GW maintains an endowment, it is neither feasible nor sustainable for GW to use endowment funds or other revenue sources, such as student tuition, to offset shortfalls in indirect cost recovery, for several reasons:

- a. Approximately 34% of GW's endowment is restricted to specific donor-designated purposes, such as scholarships, faculty chairs, and academic programs. GW is not legally permitted to use those funds to cover research infrastructure costs.
- b. Even the portion of the endowment that is unrestricted is subject to a carefully managed annual payout, typically around 4.5%, to ensure long-term financial stability for the institution. The payment from the unrestricted endowment is a critical funding source for GW's annual budget. Using any of this funding for research infrastructure costs would require redirecting it from different University obligations and needs.
- c. As a non-profit institution, GW reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps. In other words, unlike for-profit organizations, GW does not generate significant

surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid support for students.

21. Moreover, absorbing the cost of a lower indirect cost rate, even if it were possible, would create long-term budget pressures on GW—which would in turn force reductions in key investments supporting GW’s faculty, students, staff, research, and teaching infrastructure, as well as other critical activities needed to maintain GW’s academic excellence.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 10, 2025, at The George Washington University located in Washington, D.C.

/s/ Robert H. Miller

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